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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,577	10/23/2003	Lilip Lau	PARCR 65971	1087

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FULWIDER PATTON
6060 CENTER DRIVE
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EXAMINER	
GILBERT, SAMUEL G	
ART UNIT	**PAPER NUMBER**
3735	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,577	LAU ET AL.	
	Examiner	Art Unit	
	Samuel G. Gilbert	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54,55,57,60-63 and 66-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54,55,57,60-63 and 66-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/2/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 3/2/2006 has been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54,55, 57, 60-63 and 67-70 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Field(1,682,119).

The examiner is taking only element –2- a device formed of a plurality of rows of spring elements as shown in Figure 3. The device appears to be identical to the embodiment set forth in Figures 9A and 9B in the applicants specification.
It is the examiner's position that the device of Field inherently performs as claimed because the structure is identical to that which is set forth by the applicant.

Claims 54, 55, 57, 60, 61, and 66-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Bessler et al (5,855,601).

Bessler et al teaches a heart valve stent member as shown in Figure 1 and Figure 4 as elements –21- and –34-. The stent is formed by a series of springs. Figure 5 shows a compressed state.. The stent may be made of Nitinol, column 6 line 5. It is

the examiner's position that the spring strip inherently has the same properties as claimed because the spring strip is identical to the applicant's structure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 54, 55, 57, 60-63 and 66-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jayaraman (6,360,749) in view of Lau et al (6,517,570).

Jayaraman teaches a medical device, figures 6B, 7B, 7C, 8A, 8B-12 and 14 for treating the heart including elastic bands adapted to extend circumferentially around an outer surface of the heart but does not teach the material including a plurality of hinge elements. Jayaraman does set forth that stent graft materials may be used column 12 lines 19-29. Lau et al. sets forth a plurality of embodiments of stent graft material formed by a plurality of hinge elements, the embodiments of figures 3, 4, 5, 6, 8, 10, 11, 12, teach non-overlapping hinge elements. Lau et al sets forth that the hinged elements provide the advantage of being foldable to be delivered intraluminally, kink-resistant and self-expanding. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select the stent graft material taught by Lau et al. to be used for the stent graft material set forth to provide the benefits as described above to the cardiac treatment device of Jayaraman. Lau et al. further teaches the use of non-

overlapping hinge elements with torsion bars provide the advantage of allowing the device to be formed from a flat sheet and having torsional balance by spreading the load when the material is folded into a small diameter, column 12 lines 1-8.

Claim 55 - the hinge elements of Lau et al are "self-sizing" and the cardiac device of Jayaraman is adapted to extend circumferentially around the heart.

Claim 57 - Jayaraman is adapted to extend circumferentially around the heart and the hinge elements of Lau et al are inherently "self-tensioning".

Claims 60 and 61 – the compliance is an inherent feature of the hinge elements set forth in figures 1A-1E of Lau et al.

Claim 62 – Jayaraman teaches strips that extend circumferentially around the heart.

Claim 63 – the material of Lau et al. provide a compressible to a low profile. Further Jayaraman teaches minimally invasive delivery, applicant's attention is invited to column 11 lines 32-44. The term minimally invasive delivery diameter is a broad term and almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Claim 66 – Lau et al teaches the use of Nitinol, column 12 lines 31 and 32.

Claim 67 – the Nitinol hinge elements of Lau et al inherently have a deformed shape and a recovered shape.

Claim 68 - the hinges of Lau et al. provide a compressible to a low profile, column 1 lines 9-16. The term minimally invasive delivery diameter is a broad term and

almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Claim 69 - the hinges of Lau et al. provide a compressible to a low profile, column 1 lines 9-16. The term minimally invasive delivery diameter is a broad term and almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Claim 70 - the hinges of Lau et al. provide a compressible to a low profile, column 1 lines 9-16. The term minimally invasive delivery diameter is a broad term and almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54, 55, 57, 60-63 and 66-70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a device for applying a compressive force to the heart applied epicardially(outside the heart), does not reasonably provide enablement for a device for applying a compressive force to the heart applied endocardially(not outside the heart). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The applicant argues that the device as now claimed may be applied either endocardially or epicardially, however it is the examiner's position that the applicant's specification has only enabled an epicardial device and does not enable the endocardial device. The applicant has not set forth any description or drawings of the applicant's device being used inside the heart. Further, the method for implanting the device as described by the applicant is incapable of placing the device inside the heart of a patient, therefore, the applicant has not enabled the use of the device inside the heart. Even if the device as set forth could be used endocardially, the device as set forth would not be capable of applying a compressive force to the heart. The applicant has not enabled any anchor means for use inside the heart required for the device as disclosed to apply a compressive force to the heart. Further, the applicant has failed to teach how the disclosed device would be made with the required anchors. Finally, the applicant's specification actually teaches away from using an endocardial device, applicant's attention is directed to page 1 line 27 through page 2 line 10.

Response to Arguments

Applicant's arguments filed 1/31/2006 have been fully considered but they are not persuasive.

In the second paragraph the applicant has set forth an example relating to claim 54 and states "statements of intended use have been given no weight by the Examiner,

and therefore should not form a basis for the rejection of the claim as well.", which is unclear to the Examiner.

The examiner agrees that the claims as amended are broader than the previous claims which required a device adapted to extend circumferentially around an outer surface of the heart.

In the last paragraph of page 4 the applicant argues that claim 54 includes spring elements formed from a Nitinol alloy. In response the examiner would like to point out that Claim 54 does not require the use of a Nitinol alloy. Further, while dependant claim 66 requires the use of Nitinol none of the claims require a "nitinol alloy".

Also the applicant argues that the Jayaraman reference does not teach or suggest a plurality of spring elements or "the spring elements being configured to be delivered minimally invasively". The Examiner agrees and as previously set forth by the examiner the Jayaraman reference was not used alone but in an obviousness rejection in view of Lau et al. In response to applicant's arguments against the reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The applicant continues by arguing Jayaraman is completely devoid of any teaching of how to deliver the band –20- in a minimally invasive manner. The applicant points to column 12 lines 52-60 and the examiner has pointed to column 11, lines 32-42

where Jayaraman teaches that the bands are placed in a minimally invasive manner. The examiner disagrees with the applicant in that it is clear to one of ordinary skill in the art that Jayaraman teaches compressing the device delivering it with a catheter and then in some manner of expanding the device places the device around the heart, so it is clear that the band of Jayaraman is capable of being implanted in a minimally invasive manner. The argument is also moot because a method of implanting and expanding the band is not set forth in the claims.

Finally, the applicant argues that there is no motivation to combine Jayaraman and Lau et al. and that the technologies of Jayaraman and Lau et al are unrelated. The examiner is taking the "unrelated" argument to be indicating that Lau et al and Jayaraman are nonanalogous art.

In response to applicant's argument that Lau et al and Jayaraman are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Jayaraman sets forth that stent graft materials may be used to make the bands column 12 lines 19-29. Therefore it is the examiner's position that Lau et al is analogous art and reasonably pertinent to making the device of Jayaraman.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the examiner has pointed to the advantages provided by Lau et al as motivation to use the stent material taught by Lau et al as the stent material set forth in Jayaraman those advantages being to provide the advantage of the stent material being foldable to be delivered intraluminally, kink-resistant and self-expanding. As far as which particular material to use, Nitinol is especially preferred material as set forth in column 12 lines 20 through column 13 line 2. Numerous advantages are set forth, springy when formed into very thin sheets or small diameter wires, "super-elastic" or "pseudo-elastic" shape recovery properties; i.e., the ability to withstand a significant amount of bending and flexing and yet return to its original form without deformation, relatively high strength to volume ratio, and its overall suitability with magnetic resonance imaging technology. All of these advantages provide motivation to use Nitinol for the stent material used to make the device of Jayaraman.

The amount of work and time the applicants required to develop the spring elements does not overcome the obvious combination of Jayaraman and Lau et al.

Response to Amendment

The declarations of Lilip Lau filed on 11/21/2005; Bill Hartigan filed on 11/21/2005 and Darrell H. Ogi filed on 11/21/2005 under 37 CFR 1.131 have been reconsidered but are ineffective to overcome the Jayaraman reference.

The applicant sets forth that the claims as now written are not limited to devices used around the outside of the heart and therefore include any device that is capable of imparting a compressive force to a portion of the heart during diastole and systole.

It is the examiner's position that the broadest reasonable genus of the claims that are enabled by the applicants specification would be limited to a device that is capable of imparting a compressive force applied to the outside of the heart. After reading and considering the entire specification one of ordinary skill in the medical arts would not contemplate or know how to use of the disclosed invention inside the heart. The applicant even teaches away from the use of endocardial (inside the heart) devices page 1 line 27 through page 2 line 10.

The examiner agrees that the declarations set forth show "zig zag coil springs" and "spring members", however, these devices are used endocardially in combination with anchors, anchoring the springs to the myocardium inside the heart. Without the use of these anchors the devices set forth are incapable of providing a compressive force to any portion of the heart.

The specification does not teach any devices that are capable of applying a compressive force to the heart from inside the heart.

Figures 27a and 27b set forth inward facing anchors to anchor the device to the epicardial surface however it is the examiner's position that if the device was used inside the heart the anchors would be on the wrong side of the device to anchor the device to the inside surface of the heart. Therefore the device would not be capable of applying a compressive force to the heart while placed inside the heart.

According to 37 CFR 1.131 an applicant may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based. In the instant case it is the examiner's position that the declarations do not show prior invention of the enabled claims in the present application.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents 5,163,953 and 5,562,728 teach related spring elements.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

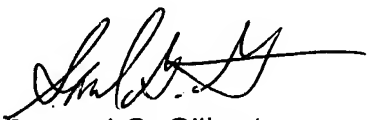
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Samuel G. Gilbert
Primary Examiner
Art Unit 3735

sgg